

REMARKS

As an initial matter, Applicants thank the Examiner for the courtesy extended in the interview on June 30, 2009 ("the Interview"), which clarified the issues remaining in the case. In response, Applicants have submitted the amendments and remarks described herein.

Claim 1-125, 129-130, 132-134, 140-143, and 145-147 are canceled; claims 135-139 and 151-156 are withdrawn; claims are 126, 128, 144, 148, 149, and 159 are amended. Upon entry of the current amendment, claims 126-128, 131, 135-139, 144, 148-159 are pending.

Support for the Amendments

Support for the amendment of the claims is found in the specification and claims as originally filed. For example, support for the amendment of claims 126, 128, and 144, which now recite *M. tuberculosis* is found at Figure 10, at page 44, lines 5-15, and at pages 52 and 58. Support for the amendment of claims 126 and 144, which now recite contacting *M. tuberculosis* cells *in vitro* is found, for example, at pages 52 and 58. Support for the amendment of claims 126 and 144, which recite incubating the cells in culture medium containing the polypeptide is found, for example, at page 21, lines 34-36, and at pages 52 and 58. Support for the amendment of claims 126, 144, 148, and 149, which now recite "95% identity" is found, for example, at page 8, lines 11-15. Support for the amendment of claim 159, which now recites that the sample is taken from a human or animal is found, for example, at page 18, line 26.

Amendment and cancellation of the claims here are not to be construed as an acquiescence to any of the rejections/objections made in the instant Office Action or in any previous Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the claims as originally filed, or substantially similar claims in one or more subsequent patent applications.

Objection to the Specification

The Examiner objects to the sequence listing filed October 27, 2006. This objection is overcome by the substitute sequence listing submitted herewith, which reflects that SEQ ID NO. 27 and Figure No. 1D are identical.

The Examiner objects to previously amended claims 128, 129, and 159. The Examiner alleges that the claims lack antecedent basis and/or that the specification and claims fail to provide support for the amendment. Applicants respectfully disagree and traverse the objection.

However, without acquiescing in any way to the rejection and in order to expedite prosecution of the application, claim 126, from which the rejected claims depend, has been amended to more clearly and fully define the invention. In particular, claim 126 now recites contacting *Mycobacterium tuberculosis* bacterial cells *in vitro* with an isolated polypeptide having at least 95% identity to amino acid residues 117-184 of SEQ ID NO:2, a polypeptide having at least 95% identity to SEQ ID NO:2, or a polypeptide comprising at least amino acid residues 117-184 of SEQ ID NO:2 and incubating the cells in culture medium containing the polypeptide, thereby resuscitating the cells. Claim 128, which depends from claim 126, now recites that the method identifies dormant, moribund or latent *Mycobacterium tuberculosis* bacterial cells in the sample. Claim 129 has been canceled without prejudice or disclaimer, thereby obviating the rejection. Accordingly, the objection to claims 126, 128 and 129 should be withdrawn.

Claim 159 now recites that the sample is taken from a human or animal. Support for this amendment is found, for example, at page 18, line 26, which recites “samples taken from an organism (e.g., human or animal).” The amendment of claim 159 clearly finds support in the specification as originally filed. Accordingly, the objection to claim 159 should also be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 128 and 129 are rejected as indefinite. The rejection of claim 128 is overcome by the present amendment, which corrects the antecedent basis, and the rejection of claim 129 is rendered moot by the cancellation of that claim.

Claims 157 and 158 are rejected as allegedly unclear for reciting that the polypeptide is “purified essentially to homogeneity.” Applicants respectfully disagree and traverse the rejection. One of skill in the art would appreciate that the polypeptide has been purified to such a degree that it is “uniform throughout in composition or structure” as evidenced in Exhibit A (<http://www.thefreedictionary.com/homogeneity>), which provides a definition of homogeneity. Moreover, Applicants describe the purification of RP factor polypeptides, for example, at pages 48 and 49. In view of this disclosure and the plain meaning of the claims, one of skill in the art would readily appreciate the meaning of purified essentially to homogeneity. Thus, this basis for the indefiniteness rejection should also be withdrawn.

The rejection of claim 159 has been obviated by the amendment of claim 128, from which claim 159 depends.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claims 126-129, 131, 144, and 148-150 are rejected as lacking enablement. Applicants respectfully disagree and traverse the rejection. However, claim 126, from which claims 127, 128, 131, and 148-150 depend, has been amended to recite methods of resuscitating dormant, moribund or latent *Mycobacterium tuberculosis* bacterial cells by contacting the *Mycobacterium tuberculosis* bacterial cells *in vitro* with an isolated polypeptide having at least 95% sequence identity with amino acid residues 117 to 184 of SEQ ID NO:2, having at least 95% sequence identity with SEQ ID NO:2; or containing at least amino acid residues 117 to 184 of SEQ ID NO:2 and incubating the cells in culture medium containing the polypeptide, thereby resuscitating the cells. Similarly, claim 144 has been amended to recite methods of resuscitating dormant, moribund or latent *Mycobacterium tuberculosis* bacterial cells by contacting the bacterial cells *in vitro* with a cell strain expressing nucleic acid molecules encoding an isolated polypeptide having at least 95% sequence identity with amino acid residues 117 to 184 of SEQ ID NO:2, having at least 95% sequence identity with SEQ ID NO:2; or containing at least amino acid residues 117 to 184 of SEQ ID NO:2 and incubating the cells and cell strain in culture medium, thereby resuscitating said cells.

In the Office action mailed January 6, 2009 (page 9, last paragraph), the Examiner acknowledged that Applicants' specification enables *in vitro* methods for resuscitating specific bacteria. Such methods are also exemplified at page 58, lines 4 and 5, where Applicants show that an *M. luteus* RP factor resuscitated dormant/latent *M. tuberculosis* cells. Accordingly, the rejection of the claims as lacking enablement should be withdrawn.

New Matter

Claims 128, 129, and 159 are further rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. Applicants respectfully disagree and traverse the rejection. However, claim 129 has been canceled without prejudice or disclaimer, thereby obviating the rejection of that claim. The rejection of claims 128 and 159 is overcome by the present amendment. Specifically, claim 126, from which the rejected claims depend, now recites

contacting *Mycobacterium tuberculosis* bacterial cells *in vitro* with an isolated polypeptide having at least 95% identity to amino acid residues 117-184 of SEQ ID NO:2, a polypeptide having at least 95% identity to SEQ ID NO:2, or a polypeptide comprising at least amino acid residues 117-184 of SEQ ID NO:2 and incubating the cells in culture medium containing the polypeptide, thereby resuscitating the cells.

Claim 128 now recites that the method identifies dormant, moribund or latent *Mycobacterium tuberculosis* bacterial cells in a sample. As detailed above, support for the amendment of claims 126 and 128 is found, for example, at Figure 10, Table 1 (page 53), and at page 52, under the heading RP Factory Activity, where Applicants show that an *M. luteus* RP factor stimulated the growth of a sample of *M. tuberculosis* bacterial cells in culture, and at page 58, where Applicants show that RP factor resuscitated *M. tuberculosis* cells isolated from a sample of murine macrophages. Clearly, claims 126 and 128 find support in the specification as originally filed. Thus, this basis for the rejection should be withdrawn.

Claim 159 now recites that the sample is taken from a human or animal. Support for this amendment is found, for example, at page 18, line 26, which recites "samples taken from an organism (e.g., human or animal)." The amendment of claim 159 clearly finds support in the specification as originally filed. Thus, this basis for the rejection should also be withdrawn.

Rejections under 35 U.S.C. § 102 Anticipation

Claims 126, 127, 131, 144, 148, and 149 are rejected as anticipated by Mukamolova et al., (Antonie van Leeuwenhoek 67:289-295, 1995; hereinafter "Mukamolova 1995") as evidenced by Mukamolova et al., PNAS 95:8916-8921, 1998). Applicants respectfully disagree and traverse the rejection. Nevertheless, as discussed with the Examiner in the Interview, claims 126 and 144, from which the remaining rejected claims depend, now recite contacting *M. tuberculosis* with isolated polypeptides having identity to or comprising amino acid residues 117 to 184 of SEQ ID NO:2 and incubating the cells in culture medium containing the polypeptide, thereby resuscitating the cells. Mukamolova 1995 fails to describe any method for resuscitating an *M. tuberculosis* cell. Thus, the rejection of the claims over Mukamolova should be withdrawn.

Rejections under 35 U.S.C. § 103 Obviousness

Claims 157 and 158 are rejected as obvious over Mukamolova in view of Harlow et al. (Antibodies: A Laboratory Manual. Cold Spring Harbor Laboratory, Chapter 5, 60-71, 1988). Applicants respectfully disagree and request withdrawal of the rejection. As discussed with the Examiner in the Interview, Mukamolova fails to teach or suggest contacting *M. tuberculosis* bacterial cells with an isolated polypeptide having identity to SEQ ID NO:2 or comprising amino acid residues 117 to 184 of SEQ ID NO:2 and incubating the cells in culture medium containing the polypeptide, thereby resuscitating the cells. In the absence of such a teaching or suggestion, claims 126 and 144 are plainly patentably distinct over Mukamolova. Because claims 157 and 158 depend from claims 126 and 144 and incorporate their features, claims 157 and 158 are also patentably distinct over Mukamolova. Accordingly, the obviousness rejection should also be withdrawn.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. Therefore, Applicants respectfully request entry of the amendments and remarks presented herein, favorable reconsideration and withdrawal of all pending rejections, and issuance of a Notice of Allowance. However, if the Examiner disagrees, Applicants respectfully request the Examiner to contact the undersigned at the telephone number indicated below to schedule a telephone conference.

Applicants believe that no fee is due to consider the present amendment. Nevertheless, the Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105.

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Respectfully submitted,

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